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5 **UNITED STATES DISTRICT COURT**  
6 **FOR THE NORTHERN DISTRICT OF CALIFORNIA**  
7 **SAN FRANCISCO DIVISION**

8 IN RE: BABY FOOD PRODUCTS  
9 LIABILITY LITIGATION

Case No. 24-MD-3101-JSC

MDL 3101

10 K.F., a minor child by and through her  
11 Proposed Guardian Ad Litem, Gaelle  
12 Jeanbaptiste,

Hon. Jacqueline Scott Corley

13 *Plaintiff,*

**COMPLAINT AND JURY DEMAND**

**Case No.**

14 vs.

15 BEECH-NUT NUTRITION COMPANY,  
16 INC.; HERO A.G.; GERBER PRODUCTS  
17 COMPANY; NESTLÉ HOLDINGS, INC.;  
18 NESTLÉ S.A.; PLUM, PBC; CAMPBELL  
19 SOUP COMPANY; SUN-MAID GROWERS  
20 OF CALIFORNIA; SPROUT FOODS, INC.  
21 and WALMART, INC.

22 *Defendants.*

23 Plaintiff by and through their counsel of record, and for their Complaint against  
24 Defendants, hereby alleges as follows:  
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## INTRODUCTION

1  
2 1. Defendants *knowingly* sold baby food products contaminated with lead, arsenic,  
3 mercury, and cadmium (collectively “Toxic Heavy Metals”). They did this knowing that Toxic  
4 Heavy Metals, when consumed by babies, are known to cause brain damage and  
5 neurodevelopmental harm. Thus, to the extent Defendants sold baby food that contained detectable  
6 amounts of Toxic Heavy Metals (collectively “Contaminated Baby Food”) those products were  
7 defective in their manufacture, design, and labeling. Babies are the most vulnerable segment of the  
8 population, and they rely on that food for healthy neurodevelopment. Defendants justify this callous  
9 disregard for the welfare of babies because, until recently, there were no regulations governing the  
10 presence of Toxic Heavy Metals in baby foods – and, because there were no regulations, they were  
11 free to do as they pleased.

14 2. This lawsuit aims to stop Defendants from poisoning infants with Contaminated  
15 Baby Food. Baby Food *should* be safe. It should *not* be contaminated with Toxic Heavy Metals.  
16 Period. By sourcing ingredients from farms that have non-detectable level of heavy metal (using  
17 sufficiently sensitive testing), avoiding certain ingredients all together, and systematically testing  
18 and screening finished products for Toxic Heavy Metals *before* the foods are released for  
19 consumption, these Defendants would be able to provide baby food products of detectable levels of  
20 Toxic Heavy Metals. And, if some levels are truly unavoidable, or if Defendants believe the  
21 identified levels are safe, then, at the very least, Defendants must warn parents/guardians/caregivers  
22 about the presence of these Toxic Heavy Metals so they can make informed decisions about what  
23 they are feeding their baby. Anything short of proper design, manufacture, and warning, is  
24 unacceptable – especially for an industry that touts itself as providing the most important sources of  
25 neurodevelopment for the most vulnerable population of society.  
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12           4.       On or about November 2018, Plaintiff K.F. was first exposed to the Contaminated  
13 Baby Food.

14                     5.       Plaintiff K.F. consumed Contaminated Baby Food Products from approximately  
15       November 2018 to May 2021.

6. The Contaminated Baby Food was purchased and consumed at least three times per day by Plaintiff K.F., a minor child with the purpose of nutrition, the use for which Defendants marketed and sold the products.

20 7. At all times, the Contaminated Baby Food was consumed by Plaintiff K.F. for the  
21 purposes that Defendants market the Baby Food Products.  
22

23           8.       After, and as a result of the consumption of Contaminated Baby Foods, Plaintiff  
24 K.F. was diagnosed with ASD on or about August 2020.

9. As a result of consuming Contaminated Baby Food, the diagnosis of ASD has required various therapies including Speech Therapy, Occupational Therapy, Physical Therapy, and Applied Behavior Analysis Therapy.



1 marketing of Baby Foods within the state of Florida.

2       14. Defendant HERO A.G., aka Hero Group (“Hero Group”) is a citizen of Switzerland,  
3 with its principal place of business located in Karl Roth-Strasse 8, 5600, Lenzburg, Switzerland.  
4 Hero Group sells baby food through its subsidiary, Beech-Nut, which it controls. For example, Hero  
5 Group made executive-level decisions for Beech-Nut concerning the acquisition of testing machines  
6 need to test baby foods for heavy metal. Hero Group, thus, has been directly involved in the tortious  
7 conduct in the United States and its various states that give rise to these lawsuits. At all relevant  
8 times, Hero Group conducted business and derived substantial revenue through Beech-Nut by  
9 manufacturing, advertising, distributing, selling, and marketing baby foods within the state of  
10 Florida.  
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12       15. The relationship between Beech-Nut and Hero Group was formed in 2005. Prior to  
13 that, starting in 1998, Beech-Nut was owned and operated by the Milnot Holding Corporation, and  
14 prior to that starting in 1989, Beech-Nut was owned and operated by Ralston Purina, and prior that,  
15 starting in 1979, Beech-Nut was owned and operated by Defendant Nestlé.  
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17       16. For the purposes of this Complaint, allegations related to Beech-Nut apply equally to  
18 Hero Group, as each Defendant exercised authority and control over the sale, manufacture, and  
19 distribution of Beech-Nut’s Contaminated Baby Foods at issue in this MDL.  
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21       17. Defendant GERBER PRODUCTS COMPANY is a citizen of Michigan and Virginia  
22 with its principal place of business located at 1812 N. Moore Street, Arlington, Virginia 22209.  
23 Gerber sells Baby Foods under the brand name Gerber. Gerber organizes its products into broad  
24 categories of “formula”, “baby cereal”, “baby food”, “snacks”, “meals & sides” “beverages” and  
25 “organic”. At all relevant times, Gerber has conducted business and derived substantial revenue  
26 from its manufacturing, advertising, distributing, selling, and marketing of Baby Foods within the  
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1 state of Florida. Gerber is a wholly owned subsidiary of and is directly controlled by Nestlé  
2 Holdings, Inc.

3       18. Defendant NESTLÉ HOLDINGS, INC. (“NHI”) is a citizen of Delaware and  
4 Virginia with its principal place of business located at 1812 N. Moore Street, Arlington, Virginia  
5 22209. According to its December 2023 annual report, “NHI is the holding company for Nestlé  
6 S.A.’s principal operating subsidiaries in the United States, which include, among others, Nestlé  
7 USA, Inc., Nestlé Purina Petcare Company, and Gerber Products Company.” NHI is a wholly  
8 owned subsidiary of Nestlé S.A. (“Nestlé”). Thus, NHI is the holding company for Nestlé that  
9 directly controls and operates Gerber – as noted by the sharing of the same address. Indeed, nearly  
10 every safety specialist that oversees the heavy metal content of Gerber baby foods, working  
11 currently in the internal project “Metallica,” are employed directly by NHI and/or Nestlé S.A. At all  
12 relevant times, NHI conducted business and derived substantial revenue through Gerber by  
13 manufacturing, advertising, distributing, selling, and marketing baby foods within the state of  
14 Florida involved in this litigation.

15       19. Defendant NESTLÉ S.A. is a citizen of Switzerland, with its principal place of  
16 business located at Avenue Nestlé 55, 1800 Vevey, Switzerland. Nestlé is a global food and  
17 beverage company with more than 2,000 brands. Nestlé sells baby food under its subsidiary, Gerber,  
18 which it directly controls through its wholly owned subsidiary NHI. Employees and scientists at  
19 Nestlé trained and set safety standards at Gerber. Indeed, in discovery ongoing in other litigation,  
20 Gerber specifically identified scientists at Nestlé to testify on behalf of Gerber regarding the safety  
21 of Gerber’s baby food products. Nestlé, thus, has been directly involved in the tortious conduct in  
22 the United States and its various states that gives rise to these lawsuits. At all relevant times, Nestlé  
23 conducted business and derived substantial revenue through Gerber and/or NHI by manufacturing,  
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1 advertising, distributing, selling, and marketing baby foods within the state of Florida.

2       20.     The relationship between Gerber, NHI, and Nestlé was formed in 2007. Prior to that,  
3 starting in 1994, Gerber was owned and operated by Novartis, one of the largest pharmaceutical  
4 companies in the world. However, in 2007, Gerber was sold to Nestlé for \$5.5 billion.  
5

6       21.     For the purposes of this Complaint, unless specifically stated otherwise, NHI and  
7 Nestlé shall be collectively referred to as “Nestlé.” Further, allegations related to Gerber apply  
8 equally to NHI and Nestlé, as each Defendant exercised authority and control over the sale,  
9 manufacture, and distribution of Gerber’s Contaminated Baby Foods at issue in this MDL.  
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11       22.     Defendant Plum, PBC (“Plum”) is a citizen of Delaware and California with its  
12 principal place of business located at 6795 N. Palm Ave., 2<sup>nd</sup> Floor, Fresno, California 93704. Plum  
13 sells Baby Foods under the brand name “Plum Organics” and has done so since 2007. Starting in  
14 2013, and until May 3, 2021, Plum was directly controlled and owned by Defendant Campbell.  
15 Plum’s products are divided into groups according to the targeted infant or toddler age and/or type  
16 of food product. For example, there are five groups designated for the youngest infants: Stage 1 (4+  
17 months old), Stage 2 (6+ months old), Stage 3 (6+ months old), “Super Puffs,” and “Little  
18 Teethers.” At all relevant times, Plum has conducted business and derived substantial revenue from  
19 its manufacturing, advertising, distributing, selling, and marketing of baby foods within the state of  
20 Florida.  
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23       23.     Defendant CAMPBELL SOUP COMPANY (“Campbell”) is a citizen of New Jersey  
24 with its principal place of business located at One Campbell Pl., Camden, New Jersey 08103.  
25 Campbell sells food and beverages and was the parent company of Plum until May 3, 2021, wherein  
26 Campbell sold Plum to Defendant Sun-Maid, a few months after the first heavy metal lawsuits were  
27 filed. Campbell sold baby food under the brand name Plum Organics through Plum. Indeed, many of  
28

1 the scientists and researchers that monitored the safety of Toxic Heavy Metals in Plum's baby foods  
2 were directly employed by Campbell or were directly controlled and trained by Campbell agents and  
3 employees. For example, it was Campbell's attorneys that responded to Congressional inquiries  
4 about heavy metals in Plum baby foods in 2019. Campbell exercised control over Plum's baby food  
5 selling in the United States until May 3, 2021. At all relevant times, Campbell conducted business  
6 and derived substantial revenues from its manufacturing, advertising, distributing, selling, and  
7 marketing of baby foods within the state of Florida.  
8

9         24. Defendant Sun-Maid Growers of California ("Sun-Maid") is a citizen of California  
10 with its principal place of business located at 6795 N. Palm Ave., Fresno, California 93711. Sun-  
11 Maid sold baby food through Plum, starting on May 3, 2021. Sun-Maid acquired Plum from  
12 Campbell on May 3, 2021. Sun-Maid has since been directly involved with all aspects of the safety  
13 and testing of Plum's baby food products. For example, metal testing is paid for directly and sent  
14 directly to Sun-Maid's scientists and executives, not directly to Plum. All major executive functions  
15 related to Plum's operation were specifically transitioned from Campbell to Sun-Maid. Like  
16 Campbell, Sun-Maid has exercised and continues to exercise direct control over the manufacture,  
17 sale, and distribution of all Plum baby foods since May 3, 2021. At all relevant times, Sun-Maid  
18 conducted business and derived substantial revenue from its manufacturing, advertising,  
19 distributing, selling, and marketing of Baby Foods within the state of Florida.  
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23         25. For the purposes of this Complaint, allegations related to Plum between 2013 and  
24 May 3, 2021 apply equally to Campbell, unless otherwise specified, and allegations related to Plum  
25 after May 3, 2021 apply equally to Sun-Maid, as each Defendant exercised authority and control  
26 over the sale, manufacture, and distribution of Plum's Contaminated Baby Foods at issue in this  
27 MDL.  
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1           30.     In particular, this Court has personal jurisdiction over Defendants for cases filed in  
 2 this District insofar as Defendants are authorized and licensed to conduct business in the State of  
 3 California, maintain and carry on systematic and continuous contacts in this judicial district,  
 4 regularly transact business within this judicial district, and regularly avail themselves of the benefits  
 5 of this judicial district.  
 6

7           31.     Additionally, Defendants caused tortious injury by acts and omissions in this judicial  
 8 district and caused tortious injury in this district by acts and omissions outside this district while  
 9 regularly doing and soliciting business, engaging in a persistent course of conduct, and deriving  
 10 substantial revenue from goods used or consumed and services rendered in this judicial district.  
 11

12           32.     Venue is proper in this District for pretrial purposed for all cases because this  
 13 litigation was centralized here under 28 U.S.C. § 1407.

14           33.     Venue is proper in this District under 28 U.S.C. § 1391(a) for cased filed here  
 15 because a substantial part of the events and omissions giving rise to those Plaintiff’ claims occurred  
 16 in this district.  
 17

18           34.     Plaintiff files this Complaint pursuant to PTO No. 5, and are to be bound by the  
 19 rights, protections, and privileges, and obligations of that PTO and other Order of the Court. Further,  
 20 in accordance with PTO No. 5, Plaintiff hereby designates the United States District Court for the  
 21 Southern District of Florida as Plaintiff’s designated venue (“Original Venue”). Plaintiff makes this  
 22 selection based upon one (or more) of the following factors.  
 23

24           ☒ Plaintiff currently resides in Broward County, Florida;

25           ☒ Plaintiff purchased and consumed Defendant(s) products in Broward County, Florida.

26           ☐ The Original Venue is a judicial district in which Defendant \_\_\_\_\_ resides, and all  
 27

28           Defendants are residents of the State in which the district is located (28 U.S.C. 1391(b)(1)).

☒ The Original Venue is a judicial district in which a substantial part of the events or omissions giving rise to the claim occurred, specially (28 U.S.C. 1391(b)(2)): Plaintiff purchased and used the subject Contaminated Baby Food Products, as well as the general location of the Plaintiff's diagnosis and treatment.

☐ There is no district in which an action may otherwise be brought under 28 U.S.C. 1391, and the Original Venue is a judicial district in which Defendant \_\_\_\_\_ is subject to the Court's personal jurisdiction with respect to this action (28 U.S.C. 1391 (b)(3)),

☐ Other reason (please explain): \_\_\_\_\_.

### **FACTUAL ALLEGATIONS**

#### **I. Rising Concerns Regarding the Presence of Toxic Heavy Metals in Baby Foods**

35. In October 2019, an alliance of nonprofit organizations, scientists and donors named "Happy Babies Bright Futures" ("HBBF"), dedicated to designing and implementing "outcomes-based programs to measurably reduce babies' exposures to toxic chemicals," published a report investigating the presence of Toxic Heavy Metals in baby foods. The HBBF Report tested 168 different baby foods sold on the U.S. market and concluded that "[n]inety-five percent of baby foods tested were contaminated with one or more of four toxic heavy metals- arsenic, lead, cadmium, and mercury. All but nine of the 168 baby foods contained at least one metal; most contained more than one." Specifically, the HBBF report identified "puffs and other snacks made with rice flour," "[t]eething biscuits and rice rusks," "infant rice cereal," "apple, pear, grape, and other fruit juices," and "carrots and sweet potatoes" manufactured by the Defendants as particularly high in Toxic Heavy Metals.

36. The results of the HBBF report were consistent with that of the U.S. Food and Drug

Administration (“FDA”) which had, in 2017, detected one or more of the four Toxic Heavy Metals in 33 of 39 types of baby food tested. However, the HBBF reported that “[f]or 88 percent of baby foods tested by HBBF- 148 of 168 baby foods- FDA has failed to set enforceable limits or issue guidance on maximum safe amounts.” The HBBF’s findings were by no means an outlier. Eight months prior to publication of the HBBF report, a study conducted by scientists at the University of Miami and the Clean Label Project “examined lead...concentrations in a large convenience sample of US baby foods.” The study detected lead in 37% of samples.

37. Moreover, earlier in 2017, HBBF commissioned a study to evaluate the presence of arsenic in infant rice cereal products sold in the U.S., and the potential risks to children’s neurodevelopment posed by contamination levels. The findings were concerning. The authors concluded that “exposures to arsenic from infant rice cereal approach or exceed existing health-based limits for arsenic levels...leaving little room for additional exposures from other dietary sources, such as snacks, apple juice, and drinking water... Our analyses of arsenic exposures from infant rice cereal during the first year of life suggest that these exposures are not insignificant, and may place infants at risk for adverse health effects.”

## **II. Congressional Investigation Finds Substantial Presence of Heavy Metals in Baby Foods Manufactured and/or Sold by Defendants, Sparking National Outrage**

38. On February 4, 2021, and September 29, 2021, respectively, the U.S. House of Representatives’ Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, published two reports detailing its findings that Toxic Heavy Metals—including lead, arsenic, mercury, and cadmium—were present in “significant levels” in numerous commercial Baby Food Products. Four companies—Hain, Gerber (Nestlé), Nurture (Danone), and Beech-Nut—produced internal testing policies, test results for ingredients and finished products, and documentation about what the companies did with ingredients and/or finished products that

1 exceeded their internal testing limits. Three companies—Plum (Campbell), Walmart, and Sprout—  
2 initially refused to cooperate.

3           39. Congress reported that the data submitted by the companies unequivocally revealed  
4 that a substantial number of Defendants’ finished products and/or ingredients used to manufacture  
5 the Baby Foods are tainted with Toxic Heavy Metals, namely lead, arsenic, mercury, and cadmium.  
6 And, where the Defendants did set internal limits for the amount of metals they allowed in their  
7 foods, Defendants routinely flouted their own limits and sold foods that consistently tested above  
8 their limits. Congress found the following:  
9

10           40. **Beech-Nut.** Beech-Nut, along with Hero Group, used ingredients after they tested as  
11 high as 913.4 ppb arsenic. Beech-Nut routinely used high-arsenic additives that tested over 300 ppb  
12 arsenic to address product characteristics such as “crumb softness.” On June 8, 2021, four months  
13 following the Congressional findings, Beech-Nut issued a voluntary recall of its infant single grain  
14 rice cereal and exited the rice cereal market completely. In its recall, Beech-Nut confirmed that its  
15 products exceed regulatory arsenic limits. And, Beech-Nut used ingredients containing as much as  
16 886.9 ppb lead, as well as 483 products that contained over 5 ppb lead, 89 that contained over 15 ppb  
17 lead, and 57 that contained over 20 ppb lead. In its follow up Report in September 2021 Congress  
18 specifically focused on Defendants Beech-Nut and Gerber’s infant rice cereals. Congress noted that  
19 Beech-Nut rice cereal tested up to 125 ppb inorganic arsenic and averaged 85.47 ppb inorganic  
20 arsenic. Beech-Nut’s practice of testing ingredients, rather than finished products, for toxic heavy  
21 metals appears to have contributed to its failure to detect the dangerous inorganic arsenic levels in its  
22 recalled products. Lastly, Beech-Nut does not even test for mercury in baby food.

23           41. **Gerber.** Gerber along with Nestlé used high-arsenic ingredients, using 67 batches of  
24 rice flour that had tested over 90 ppb inorganic arsenic. Nestlé and Gerber used ingredients that  
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1 tested as high as 48 ppb lead; and used many ingredients containing over 20 ppb lead. Nestlé and  
 2 Gerber rarely test for mercury in their baby foods. In the September 2021 follow-up Congressional  
 3 report, it was revealed that Nestlé and Gerber’s rice cereal tested up to 116 ppb inorganic arsenic,  
 4 and their average rice cereal product contained 87.43 ppb inorganic arsenic, which is even higher  
 5 than the amount contained in Beech-Nut’s average rice cereal product. While Beech-Nut recalled  
 6 some of its products and completely discontinued sales of its rice cereal, Nestlé and Gerber have  
 7 taken no such actions to protect children.  
 8

9           42.     **Plum.** Plum, along with Campbell, refused to cooperate with the Congressional  
 10 investigation. Instead of producing any substantive information, Campbell provided Congress with a  
 11 self-serving spreadsheet declaring that every one of its products sold through Plum “meets criteria”,  
 12 while declining to state what those criteria were. Disturbingly, Campbell admitted that for mercury  
 13 (a powerful neurotoxin), Campbell and Plum have *no criterion* whatsoever, stating: “No specific  
 14 threshold established because no high-risk ingredients are used.” However, despite Campbell and  
 15 Plum having no mercury threshold, Campbell and Plum still marked every food as “meets criteria”  
 16 for mercury. Congress noted that “[t]his misleading framing—of meeting criteria that do not exist—  
 17 raises questions about what [Plum’s] other thresholds actually are and whether they exist.” This  
 18 suspicion is confirmed by HBBF’s independent testing which confirms the present of Toxic Heavy  
 19 Metals in Campbell and Plum Baby Food, which found excess levels of lead, arsenic, and mercury in  
 20 Campbell and Plum’s Just Sweet Potato Organic Baby Food; Just Peaches Organic Baby Food; Just  
 21 Prune Organic Baby Food; Pumpkin Banana Papaya Cardamom; Apple, Raisin & Quinoa Organic  
 22 Baby Food; Little Teethers Organic Multigrain Teething Wafers-Banana with Pumpkin; and Mighty  
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1 Morning Bar-Blueberry Lemon-Tots. Furthermore, as discussed further below, based upon  
2 information and belief, Plaintiff submit that Campbell and Plum's pattern and practice of failing to  
3 test ingredients, willingly flouting their own internal standards, and selling products notwithstanding  
4 internal acknowledgement of their high metal content, follows that of the other Defendants discussed  
5 in this Complaint, and discovery here will further flesh out the extent of Campbell and Plum's  
6 culpable conduct.

8       43.     **Sprout.** Sprout initially refused to cooperate with the House Subcommittee's  
9 investigation, and as such the Subcommittee stated that Sprout's failure to respond "raises serious  
10 concerns about the presence of toxic heavy metals in its baby foods." The Subcommittee noted that  
11 independent data from the HBBF Report confirmed that Sprout's baby foods are indeed tainted. For  
12 example, the HBBF Report observed that Sprout's Organic Quinoa Puffs Baby Cereal Snack-Apple  
13 Kale contained 107 ppb total arsenic, 47 ppb inorganic arsenic, 39.3 ppb lead, and 41.5 ppb  
14 cadmium.

16       44.     As outlined in the Subcommittee's Addendum Report, Sprout eventually provided a  
17 "handful of documents" to the Subcommittee, and the documents provided "displayed a lax  
18 approach to testing for toxic heavy metals in its baby food." Sprout relies on its ingredients suppliers  
19 to test their ingredients for toxic heavy metals and only asks the suppliers to test once a year. Upon  
20 information and belief, despite its representations to the Subcommittee, Sprout did not require its  
21 raw ingredient suppliers to provide yearly heavy metal test results prior to the Subcommittee's  
22 inquiry into the company. Sprout provided only 11 toxic metal test results to the Subcommittee  
23 stating that "[b]ecause Sprout requires annual testing for heavy metals for its ingredients, rather than  
24 by lot, Sprout is unable to provide testing information for each lot as requested." The Subcommittee  
25 called this testing "the most reckless among baby food sellers on the market."  
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1           45.     **Walmart.** Walmart refused to cooperate with the House Subcommittee's  
2 investigation into its baby food products, and as such, the Subcommittee was "greatly concerned"  
3 that Walmart "might be obscuring the presence of higher levels of toxic metals in their baby food  
4 products." The Subcommittee noted that independent data from HBBF Report confirmed that  
5 Walmart's baby foods are indeed tainted. For example, the HBBF Report observed that one of  
6 Walmart's products contained 56.1 ppb total arsenic, and 26.1 ppb cadmium. Another product  
7 contained 108 ppb total arsenic, 66 ppb inorganic arsenic, 26.9 ppb lead, and 2.05 ppb mercury.  
8

9           46.     Following the publication of the Subcommittee Report, Walmart provided documents  
10 to the Subcommittee. On September 29, 2021, the House Subcommittee released a subsequent report  
11 entitled "New Disclosures Show Dangerous Levels of Toxic Heavy Metals in Even More Baby  
12 Foods." The Subcommittee report addendum described the documents from Walmart as "revealing a  
13 concerning lack of attention to toxic heavy metal levels in baby food and an abandonment of its  
14 previously more protective standards." Walmart does not appear to conduct any testing of its baby  
15 food products. Walmart sets maximum arsenic and lead levels and asks the manufacturer of its  
16 private label to self-certify, but Walmart does not appear to collect any test data or check the  
17 accuracy of those certifications. Walmart does not require any mercury or cadmium testing and does  
18 not set any standards for mercury or cadmium levels.  
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21           47.     The metal concentrations discussed above and further below surpass the limits  
22 allowed by U.S. regulatory agencies. There are no FDA final regulations governing the presence of  
23 Toxic Heavy Metals in the majority of Baby Foods with the exception of 100 ppb inorganic arsenic  
24 in infant rice cereal and proposed (not yet final) limits for lead in certain baby food categories. To  
25 the extent such regulations exist, the quantities of Toxic Heavy Metals in Defendants' Baby Foods  
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1 exceed any permissible FDA levels. To be sure, the FDA has set the maximum contaminant levels  
2 (“MCL”) in bottled water at 10 ppb inorganic arsenic, 5 ppb lead, and the EPA has capped the  
3 allowable level of mercury in drinking water at 2 ppb. However, these limits were created in  
4 reference to *adult* exposure, not infants. Compared to these thresholds, the test results of the  
5 Defendants’ baby foods and their ingredients are multiple folds greater than the permitted metal  
6 levels. Moreover, compounding these troubling findings, the Defendants set internal limits for the  
7 presence of Toxic Heavy Metals in their foods that were, themselves, dangerously high and then  
8 routinely failed to abide by those inadequate standards, as discussed below.

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11 48. As Congress observed, the Defendants have willfully sold—and continue to sell—  
12 contaminated Baby Foods notwithstanding their full awareness of these unacceptably high levels of  
13 Toxic Heavy Metals in their products.

14 **III. Defendants Engaged in a Pattern and Practice of Selling Contaminated Baby Foods and**  
15 **Failed to Reduce Metal Levels**

16 49. Several factors drive the Toxic Heavy Metal contamination of Defendants’ baby  
17 foods, all of which are within Defendants’ control.

18 50. *First*, at various times, all Defendants sourced ingredients that contained elevated  
19 levels of Toxic Heavy Metals. These ingredients were then used to manufacture the baby foods  
20 consumed by Plaintiff, thereby exposing Plaintiff to Toxic Heavy Metals that cause brain damage  
21 and other neurodevelopmental harm. One way for Defendants to “deal” with this issue involved  
22 relegating any testing of Toxic Heavy Metals to suppliers and co-manufacturers, who were required  
23 to certify that Toxic Heavy Metals were below a certain threshold. Defendants would audit those  
24 results, discover that the reported certifications were false or inaccurate, and then take no action to  
25 stop the use of those ingredients or finished products.  
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1           51.     *Second*, some Defendants implemented dangerously high internal limits  
2 (“specifications” or “specs”) for the maximum level of Toxic Heavy Metals that Defendants allowed  
3 in the baby foods. Such high limits—untethered to any consideration of the low levels at which  
4 metals are capable of damaging babies’ brains—allowed Defendants to source and use ingredients  
5 that contained elevated Toxic Heavy Metals to manufacture the baby foods consumed by Plaintiff. In  
6 the highly competitive and lucrative baby food market, using contaminated ingredients allows each  
7 Defendant to retain greater market share.

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9           52.     *Third*, some Defendants failed to implement any internal specifications for the  
10 amount of Toxic Heavy Metals allowed in ingredients or finished baby foods. By simply not looking  
11 at the issue, certain highly contaminated ingredients and finished products were allowed to be used  
12 and sold to consumers. This would happen notwithstanding the Defendants’ specific knowledge of  
13 the risk of Toxic Heavy Metals and their presence in ingredients and finished products.

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15           53.     *Fourth*, Defendants did not routinely adhere to their own internal metal specifications  
16 or standards, allowing contaminated ingredients and finished products to be released as “exceptional  
17 releases” or other simpler terminology. This resulted in ingredients being used and baby foods  
18 manufactured and sold that contained levels of Toxic Heavy Metals far higher than what was  
19 internally set by Defendants. In other instances, Defendants would test products that had been put  
20 on the market after-the-fact, learn about the products containing extremely high levels of Toxic  
21 Heavy Metals, and then take no action to recall the product or warn consumers about the issue.

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23           54.     *Fifth*, upon information and belief, Defendants’ manufacturing practices also  
24 contributed to contamination. For example, the water used at some of the facilities where the baby  
25 foods were manufactured contained Toxic Heavy Metals which, in turn, ended up in the finished  
26 baby food product sold for consumption by babies.  
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1           55.     **Beech-Nut.** Beech-Nut and Hero Group did not test their finished baby foods for  
2 heavy metals, only ingredients. And, Beech-Nut and Hero Group regularly accepted ingredients  
3 testing far higher than its internal limits for Toxic Heavy Metals. They justified such deviations as  
4 “exceptional releases.” For example, Beech-Nut and Hero Group “exceptionally released” 160,000  
5 pounds of sweet potatoes for their baby food products notwithstanding the ingredient testing twice as  
6 high as Beech-Nut’s internal heavy metal limit for lead.

7  
8           56.     Moreover, Beech-Nut and Hero Group did not adequately test their ingredients for  
9 heavy metals by limiting ingredient lots and ingredient quantities that were subject to metal testing.  
10 For example, if a supplier supplied ingredients below a certain amount, they would not test anything  
11 and simply use the ingredient in the finished product. Furthermore, in deciding to violate their own  
12 internal limits, Beech-Nut and Hero Group took advantage of the fact that the FDA does not  
13 routinely test baby foods for Toxic Heavy Metals.

14  
15           57.     Upon information and belief, Beech-Nut and Hero Group went so far as to manipulate  
16 their testing practices by continually re-testing ingredients that tested above their internal specs until  
17 they obtained a result that was at or below their internal specs, knowing full well that the ingredient  
18 was nonetheless contaminated.

19  
20           58.     Beech-Nut and Hero Group’s internal specifications varied wildly by ingredient, with  
21 Beech-Nut allowing very high levels of Toxic Heavy Metals for certain ingredients, and insisting on  
22 lower levels for others. Thus, certain products like rice flour, were allowed to have very high levels  
23 of metals like arsenic and lead, even in products that were 90% or more rice. Beech-Nut and Hero  
24 Group did this because there were no regulations governing Toxic Heavy Metal in baby food and,  
25 therefore, to remain competitive in the baby food marketplace, Beech-Nut used contaminated  
26 ingredients because they were readily available.  
27  
28

1           59.     **Gerber.** Gerber, NHI, and Nestlé tested ingredients and, occasionally, finished  
2 products. However, while Gerber, NHI, and Nestlé were the only Defendants to test both ingredients  
3 and finished products with any regularity, they set high heavy metal limits that rendered their food  
4 unsafe. For baby foods generally, between 2012 and 2019, Gerber, NHI, and Nestlé set a limit of 40  
5 ppb for lead, 20 ppb for arsenic, and 10 ppb for mercury. For infant rice cereal, between 2012 and  
6 2017, Gerber, NHI, and Nestlé set a lead limit of 100 ppb, with a “target” of 50 ppb in 2016 and  
7 2017. Between 2018 and 2019, Gerber, NHI, and Nestlé set a lead limit for 50 ppb. For arsenic in  
8 rice cereal, between 2012 and 2015, Gerber, NHI, and Nestlé did not have a limit, merely a target of  
9 100 ppb. Then, between 2016 and 2018, it set the arsenic limit at 100 ppb. By 2019, Gerber, NHI,  
10 and Nestlé increased the arsenic limit to 130 ppb for cereals with 90% rice (and kept the limit at 100  
11 ppb for other cereals). For snack foods, Gerber, NHI, and Nestlé had a lead limit of 150 ppb  
12 between 2012 and 2014. It was reduced to 100 ppb in 2016 and 2017, and then went down to 50 ppb  
13 in 2018 and 2019. There was no limit for arsenic in snack food prior 2016, just a “target” of 100  
14 ppb. Then a 100-ppb arsenic limit was set starting in 2016. For both infant cereal and snacks,  
15 Gerber, NHI, and Nestlé imposed a 30-ppb limit for mercury in infant cereal between 2012 and  
16 2016, and reduced it to 10 ppb from 2017 onward. With these exceptionally high limits, Gerber,  
17 NHI, and Nestlé sold baby foods that were dangerous for infant consumption. They did this  
18 knowingly.  
19

20           60.     Gerber, NHI, and Nestlé would also audit and re-test Toxic Heavy Metal results  
21 submitted by suppliers, and find that the certification from suppliers were incorrect or false. Gerber,  
22 NHI, and Nestlé would nonetheless use the certified results and release products despite the  
23 ingredients not meeting specifications or being safe for infant consumption.  
24

25           61.     Gerber, NHI, and Nestlé often used high-arsenic ingredients, for example, using 67  
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28

1 batches of rice flour that had tested over 90 ppb inorganic arsenic. Furthermore, Gerber, NHI, and  
2 Nestlé regularly sold baby food products testing over 100 ppb arsenic, at times reaching 116 ppb,  
3 and their average rice cereal product contained 87.43 ppb inorganic arsenic. Indeed, this is why  
4 Congress noted that “Gerber’s organic rice cereal is dangerous...” In other instances, Gerber  
5 permitted as much as 300 ppb of arsenic in the rice flour ingredient used to manufacture its U.S.  
6 baby foods, notwithstanding the fact that Gerber often implemented stricter standards for baby foods  
7 sold in other countries.  
8

9           62. Gerber’s baby foods are also contaminated with elevated levels of lead. Gerber, NHI,  
10 and Nestlé used ingredients that tested as high as 48 ppb lead and used many ingredients containing  
11 over 20 ppb lead. Furthermore, Gerber, NHI, and Nestlé sold baby food products testing at and/or  
12 above 50 ppb of lead. Indeed, Gerber, NHI, and Nestlé have historically permitted as much as 150  
13 ppb lead in their baby food products. Although Gerber, NHI, and Nestlé were fully aware that it was  
14 very feasible to source lower-lead ingredients, they proceeded to use high-lead ingredients in their  
15 baby foods. Gerber, NHI, and Nestlé rarely test for mercury in their baby foods. This is  
16 notwithstanding the fact that mercury is known to contaminate ingredients such as rice and poses a  
17 severe risk to babies’ brain development.  
18

19           63. The February 4, 2021 Congressional Report found Gerber carrots tested for cadmium  
20 at levels above 5 ppb, with some containing more than 87 ppb of cadmium. These are exceptionally  
21 high levels.  
22

23           64. Moreover, compounding these troubling findings, Gerber, NHI, and Nestlé  
24 historically only tested certain ingredients of its baby food products and only occasionally tested the  
25  
26  
27  
28

1 finished products consumed by babies. It was not until recently that Gerber, NHI, and Nestlé started  
2 to implement finished product testing on a more regular basis.

3           65.     Gerber, NHI, and Nestlé have known since at least the 1990s that inorganic arsenic  
4 was neurotoxic and caused developmental issues. Despite this knowledge, in 2012, when Gerber's  
5 infant rice cereal was on the front page of a Consumer Report article on arsenic, a Gerber  
6 spokesperson told the public that arsenic in baby food posed no health risk.

7  
8           66.     **Plum.** Plum was founded in 2007 and has sold a wide variety of baby food products  
9 under the name Plum Organics since that time. Plum was owned and controlled by Campbell from  
10 roughly 2013 until roughly May 2021 when Plum was sold to Sun-Maid.

11  
12           67.     Despite Plum's public facing statements that "little ones deserve the very best food  
13 from the very first bite" and despite understanding that environmental toxins like heavy metals can  
14 cause neurodevelopmental disorders in children, Plum and Campbell/Sun-Maid did very little to  
15 ensure that the Plum baby food products marketed for consumption by children are not contaminated  
16 with dangerous levels of heavy metals. For example, though Plum and Campbell/Sun-Maid knew  
17 that the heavy metal contents of the ingredients used in its products varied by growing region and  
18 supplier, they did not undertake an effort to source ingredients with the lowest amount of heavy  
19 metals available. And, despite knowing that certain ingredients carry a higher risk for heavy metal  
20 contamination, Plum and Campbell/Sun-Maid did not reformulate their products to ensure that they  
21 were being made with the lowest achievable amount of heavy metals.

22  
23  
24           68.     Plum and Campbell failed to set limits on the amount of heavy metals that could be  
25 present in Plum's finished baby food products. From 2007 to at least April 2021, they did not set  
26 *any* limits for the amount of lead, arsenic, mercury, cadmium, or aluminum that their finished  
27 products could contain.  
28

1           69. Plum and Campbell also failed to set limits on the amount of heavy metals that could  
2 be present in the ingredients used in Plum's baby food products. Prior to 2016, they did not set  
3 limits for the amount of heavy metals that could be present in the ingredients used in Plum products.  
4 When Plum and Campbell did begin to implement heavy metal limits for Plum ingredients (in or  
5 around 2017), it did so only for lead, arsenic, and cadmium. As of April 2021, Plum and Campbell  
6 still had no limits for the amount of mercury and aluminum that could be in the ingredients used in  
7 their baby food products.  
8

9           70. When Plum did set some heavy metal limits (for lead and arsenic for ingredients  
10 only) it set those limits several times in excess of what was achievable for most ingredients. For  
11 example, despite certain fruits and vegetables normally containing less than 5 ppb lead or arsenic,  
12 Plum set the heavy metal limits for all Plum ingredients for lead and arsenic at 100 ppb. And, even  
13 still, despite setting these limits dangerously high, Plum and Campbell/Sun-Maid still utilized  
14 ingredients that tested in excess of those limits.  
15

16           71. Plum and Campbell/Sun-Maid also conducted very little oversight of their co-  
17 manufacturers to ensure that the heavy metal limits for ingredients used in Plum products were  
18 adhered to. For example, prior to 2017, Plum and Campbell did not require the ingredient suppliers  
19 they contracted with to submit heavy metal testing data but instead relied on supplier assurances that  
20 the ingredients did not contain heavy metals and/or complied with all government regulations  
21 regarding heavy metals. When Plum and Campbell/Sun-Maid did begin to require testing on some  
22 of the ingredients used in its products for lead and arsenic, those efforts were scattershot and did not  
23 extend to all lots of all ingredients used in Plum baby food products. Where verification testing was  
24 conducted on ingredients, it was often done in an unaccredited lab.  
25  
26  
27  
28

1           72.     Despite not having a comprehensive ingredient testing program to ensure that Plum  
2 food marketed for babies was not contaminated with Toxic Heavy Metals, Plum and Campbell/Sun-  
3 Maid also did not conduct heavy metal testing on Plum products prior to sale. Plum only first  
4 conducted finished product testing in the wake of public reports that exposed Plum baby food  
5 products as being contaminated with dangerous levels of heavy metals. Upon information and  
6 belief, no rigorous heavy metal testing program on ingredients and finished product was ever  
7 implemented and Plum and Campbell/Sun-Maid continued and continue to sell baby food  
8 contaminated with elevated levels of heavy metals without first testing to ensure their safety.  
9

10           73.     **Sprout.** Sprout's baby foods are contaminated with Toxic Heavy Metals. For  
11 example, the HBBF Report observed that Sprout's Organic Quiona Puffs Baby Cereal Snack-Apple  
12 Kale contained 107 ppb total arsenic, 47 ppb inorganic arsenic, 39.3 ppb lead, and 41.5 ppb  
13 cadmium. These levels are all highly dangerous for consumption by an infant.  
14

15           74.     Sprout's testing and oversight are extremely lacking. Sprout claims that it relies on  
16 its ingredients suppliers to test their ingredients for some Toxic Heavy Metals and only asks the  
17 suppliers to test once a year—a frequency that cannot ensure any safety. However, upon  
18 information and belief, despite its representations, Sprout did not require its raw ingredient suppliers  
19 to provide yearly heavy metal test results prior to the Subcommittee's inquiry into the company.  
20

21           75.     Sprout provided only 11 toxic heavy metal test results to the Subcommittee stating  
22 that "[b]ecause Sprout requires annual testing for heavy metals for its ingredients, rather than by lot,  
23 Sprout is unable to provide testing information for each lot as requested." The Subcommittee called  
24 this testing the "the most reckless among baby food sellers on the market."  
25

26           76.     Since it began testing in 2021, the results observed in Sprout's food are disturbing.  
27 For example, testing showed, on average, over 300 ppb of arsenic in Sprout's puff products, with  
28



1 levels as high as 470 ppb. Testing on other Toxic Heavy Metals also shows exceptionally high  
 2 levels in various Sprout products. Sprout’s consistent failure to test, regulate, or monitor their baby  
 3 food products, has led to the sale of an alarming number of baby food products that were  
 4 contaminated with Toxic Heavy Metals.

5  
 6 77. Internal documents within Sprout confirm that the companies were aware of these  
 7 issues, even made jokes about it, but took no action to take reasonable care to avoid harm to infants  
 8 until Congress blew the whistle on Sprout—and then, only after Sprout initially refused to cooperate  
 9 with a Congressional investigation.

10  
 11 78. Despite these findings, Sprout continues to market its products as safe, stating on its  
 12 website, “[i]f it isn’t safe, healthy, and delicious, we don’t make it.” Considering they never tested  
 13 their products prior to 2021, this statement is, at best, an overstatement.

14 79. **Walmart.** Walmart sold baby food under a “private” brand called “Parent’s Choice”,  
 15 which was manufactured by a different supplier but branded, promoted, and sold as a Walmart  
 16 product. Walmart did not test it for Toxic Heavy Metals whatsoever. Instead, Walmart required  
 17 certain specifications be met for the products provided by its suppliers, which included some limits  
 18 of heavy metals. These specifications were not enforced in any way. Walmart did not require the  
 19 submission of testing from suppliers, nor did it do any of its own testing.

20  
 21  
 22 80. The only efforts to police Toxic Heavy Metals in their Parent’s Choice baby food  
 23 involved generic specifications for lead and arsenic—there were no other specifications or limits for  
 24 other Toxic Heavy Metals—which for most baby food products resulted in there being no limits. The  
 25 following chart reflects Walmart’s Toxic Heavy Metal specifications prior to December 2018.

Type of Food	Lead	Arsenic	Mercury	Cadmium	Aluminum
Dry baby food with no juice or nectar	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>

1	Dry baby food with juice or nectar	50 ppb	23 ppb	<i>None</i>	<i>None</i>	<i>None</i>
2	Wet baby food with no juice or nectar	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>
3	Wet baby food with juice or nectar	50 ppb	23 ppb	<i>None</i>	<i>None</i>	<i>None</i>
4	Yogurt baby food products	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>

6           81. In December 2018, Walmart changed its specification to 100 ppb of inorganic arsenic  
7 for all dry baby foods, making the products even less safe. Thus, for the vast majority of Walmart's  
8 baby food products, there was never a limit for any Toxic Heavy Metals.

#### 9           **IV. Defendants Abandon Efforts to Reduce Metal Levels in Baby Foods**

10           82. In 2019, as concerns grew over contamination of certain baby foods on the U.S.  
11 market, a consortium of the Defendants comprised of Beech-Nut, Plum/Campbell, Gerber, Hain,  
12 Nurture, and Sprout, as well as certain interested third party groups such as the Environmental  
13 Defense Fund ("EDF") and HBBF, were formed with the intention "of reducing heavy metals in  
14 young children's food."  
15

16           83. The consortium was named the Baby Food Council ("BFC"). The BFC involved the  
17 sharing of common testing data on the levels of metal contamination of Defendants' baby foods, a  
18 grant to Cornell University to further study the issue, and a proposed "voluntary Baby Food Standard  
19 to limit the amounts of heavy metals in baby food." The BFC specifically recognized the risk of  
20 neurodevelopmental harm caused by Toxic Heavy Metals to the developing brain of infants and that  
21 there were no safe levels of exposure.  
22

23           84. The Baby Food Standard "would have provided companies with a common  
24 framework for progressively reducing contaminants by regularly testing products and improving  
25 management practices, and for being transparent with consumers about the safety of their products."  
26

27           85. After several years of negotiations and discussions, including a proposed system for  
28

1 testing, the EDF and HBBF proposed voluntary limits of 1 ppb for lead. The baby food companies,  
2 however, rejected the proposal outright. Participation in the BFC was little more than a façade—  
3 they had no intention of self-regulating their products as it related to Toxic Heavy Metals.

4  
5 86. This led EDF and HBBF to leave the BFC in protest in 2021. They explained their  
6 departure publicly, noting that Defendants “all decided to backpedal on this project—even though  
7 the standard was designed to protect babies’ brain development” and provide adequate notice to  
8 consumers regarding the presence of Toxic Heavy Metals on Baby Food labeling. EDF explained:

9  
10 EDF cofounded the Council because we believed there was a shared commitment to  
11 reduce levels of lead, arsenic and cadmium in baby food products to better protect  
12 children’s developing brains from these toxins... Unfortunately, the companies chose  
13 to cease the Council’s development of a voluntary Baby Food Standard that it had  
14 begun in late 2020. The Standard would have provided companies with a common  
15 framework for progressively reducing contaminants by regularly testing products and  
16 improving management practices, and for being transparent with consumers about the  
17 safety of their products. Negotiations failed to provide an alternative approach that  
18 EDF felt was sufficient to drive down levels of lead, arsenic and cadmium in baby  
19 food.”

20  
21 87. HBBF explained:

22  
23 Healthy Babies Bright Futures is focused on tangibly reducing neurotoxic exposures  
24 to babies. The baby food companies’ refusal to jointly set limits for heavy metals in  
25 baby food has shown that the Council will no longer be the powerful mechanism for  
26 this important work that the initial plans had promised. The baby food companies’  
27 decision to stop progress on a voluntary standard for heavy metals in baby food is a  
28 disappointment...What started as dedication has turned into delay and intention has  
29 become inaction. So HBBF has decided to put our effort into other initiatives that  
30 will move the needle on this important issue.

31  
32 88. In short, the Defendants opted to continue “self-regulating,” the same self-regulation  
33 which exposed—and continued to expose—Plaintiff to Toxic Heavy Metals in Defendants’ baby  
34 foods.

35  
36 **V. The Dangers of Toxic Heavy Metals and Metal Exposure Through Consumption of**

## 1           **Baby Foods**

2           89.       According to the World Health Organization (“WHO”), Toxic Heavy Metals,  
3 specifically lead, arsenic, mercury, and cadmium pose a “major public health concern” for children.  
4 The Occupational Safety and Health Administration (“OSHA”) has warned that these metals “may  
5 build up in biological systems and become a significant health hazard.” Indeed, the Department of  
6 Health and Human Services’ Agency for Toxic Substances and Disease Registry (“ATSDR”) ranks  
7 arsenic as number *one* among substances present in the environment that pose the most significant  
8 potential threat to human health, followed by lead (second), mercury (third), and cadmium (seventh).  
9

10           90.       The threat presented by Toxic Heavy Metals to children’s health is widely shared by  
11 the global regulatory and scientific community. For example, the FDA has set an Interim Reference  
12 Level (“IRL”) of 2.2 micrograms/day for lead exposure through baby food products. That is the  
13 amount of lead exposure at or above which the agency considers associated with adverse  
14 neurodevelopmental effects in babies. The FDA, in its guidance documents for inorganic arsenic  
15 and lead in baby food products has repeatedly acknowledged the dangers of heavy metals to the  
16 neurodevelopment of infants.  
17

18           Even low lead exposure can harm children’s health and development,  
19 specifically the brain and nervous system. Neurological effects of lead exposure  
20 during early childhood include learning disabilities, behavior difficulties, and  
21 lowered IQ. Lead exposures also may be associated with immunological,  
22 cardiovascular, renal, and reproductive and/or developmental effects...Because  
23 lead can accumulate in the body, even low-level chronic exposure can be  
24 hazardous over time...Even though no safe level of lead exposure has yet been  
25 identified for children's health, the IRL serves as a useful benchmark in  
26 evaluating the potential for adverse effects of dietary lead. In particular, FDA is  
27 focused on the potential for neurodevelopmental effects from lead exposure, as  
28 review of the scientific literature indicates that *such adverse effects  
of lead consistently occur at a blood lead level associated with FDA’s IRL for  
children.* (emphasis added).

1           91. As one recent study observed, “[t]he implications of heavy metals with regards to  
 2 children’s health have been noted to be more severe compared to adults. The elements’ harmful  
 3 consequences on children health include mental retardation, neurocognitive disorders, behavioral  
 4 disorders, respiratory problems, cancer and cardiovascular diseases. Much attention should be given  
 5 to heavy metals because of their high toxicity potential, widespread use, and prevalence.” Children  
 6 and, even more so, babies have higher exposure to metals compared to adults because they consume  
 7 more food in relation to their body weight and absorb metals more readily than adults by 40 to 90%.

8           92. The mechanisms needed to metabolize and eliminate heavy metals are comparatively  
 9 undeveloped in childhood, with babies having weaker detoxifying mechanisms and poorer immune  
 10 systems than adults. For example, liver pathways that in adulthood metabolize absorbed arsenic do  
 11 not mature until mid-childhood; un-excreted arsenic thus continues to circulate and is deposited in  
 12 other organs. According to Linda McCauley, Dean of the Nell Hodgson Woodruff School of Nursing  
 13 at Emory University, who studies environmental health effects, “[n]o level of exposure to these  
 14 [heavy] metals has been shown to be safe in vulnerable infants.”

15           93. Thus, “the major windows of developmental vulnerability occur during infancy and  
 16 early childhood due to continuing brain development after birth.” In short, even small amounts of  
 17 exposure to Toxic Heavy Metals can have devastating health outcomes for babies and children.

18           **A. Exposure to Toxic Heavy Metals Has Been Consistently Associated with**  
 19 **Neurodevelopmental Harm, i.e., Autism and ADHD in Pediatric Populations**

20           94. It is well-known that exposure to Toxic Heavy Metals in early life can interfere with  
 21 neurodevelopment at exceedingly low levels of exposure. And, one of the ways in which such  
 22 interference with neurodevelopment can present in a child is in the form of the neurodevelopmental  
 23 disorders ASD and ADHD. As the U.S. Centers for Disease Control observed in its 2020  
 24 Toxicological Profile for Lead, at just  $\leq 10$   $\mu\text{g/dL}$ : “The following neurobehavioral effects in children  
 25  
 26  
 27  
 28

1 have been associated with [lead]: “Altered mood and behaviors that may contribute to learning  
2 deficits, including *attention deficits, hyperactivity, autistic behaviors*, conduct disorders, and  
3 delinquency.” (emphasis added). Likewise, the NIH states: “prenatal and early childhood exposure  
4 to heavy metals...may be linked to autism spectrum disorder.”  
5

6 95. Such conclusions have likewise been reached by a consortium of the country’s  
7 leading epidemiologists, pediatricians, and medical groups, noting that Toxic Heavy Metals such as  
8 lead and mercury are “prime examples of toxic chemicals that can contribute to learning, behavioral,  
9 or intellectual impairment, as well as specific neurodevelopmental disorders such as ADHD or  
10 autism spectrum disorder.”  
11

12 96. Multiple studies, reviews, and meta-analyses conducted throughout various parts of  
13 the world over the last decade have consistently observed that early life exposure to heavy metals  
14 can cause brain injury and, specifically, brain injury which manifests as ASD.  
15

16 97. For example, four meta-analyses published in 2014, 2017, 2019 and 2020,  
17 respectively, observed consistent associations between exposure to arsenic, cadmium, and mercury  
18 and ASD in children; with the authors in all three studies recommending – based on the data – that  
19 exposure to such metals in children be reduced as much as possible, and one of the study authors  
20 specifically concluding that “Results of the current meta-analysis revealed that mercury is an  
21 important causal factor in the etiology of ASD.”  
22

23 98. In a recent 2017 NIH-funded prospective observational study, the authors examined  
24 the risk of ASD outcome in twins based on their respective body burden of lead. The study  
25 concluded in no uncertain terms that “prenatal and early childhood disruption (excess or deficiency)  
26 of multiple metals during critical developmental windows is associated with ASD, and suggests a  
27 role for elemental dysregulation in the etiology of ASD.”  
28

1           99.     Similarly, a large, prospective study from 2016 in Korean school children observed  
2 that low levels of lead exposure in early life are associated with autism, the authors specifically  
3 concluding: “even low blood lead concentrations...are associated with more autistic behaviors...  
4 underscoring the need for continued efforts to reduce lead exposure.”

5  
6           100.   Studies have repeatedly observed strong associations between exposure to cadmium  
7 and aluminum and neurodevelopmental disorders such as ASD, as observed by a recent study:  
8 “Environmental exposure to...cadmium (Cd)... and aluminum (Al) has been associated with  
9 neurodevelopmental disorders including autism spectrum disorder (ASD).” For example, a study  
10 from 2014 evaluated the body burden of lead, cadmium, and arsenic in children with autism  
11 compared to controls and noted that, in addition to lead and arsenic, “our study demonstrated  
12 elevation in the levels of...cadmium...in a child with autism,” while an earlier study noted that  
13 “autism may be associated with significant alterations of some rare element concentrations,  
14 including Cd...” Such results have been confirmed by meta-analyses which “*show significant*  
15 *associations* between ASD and the metals Al [and] Cd.” And, such earlier data is further supported  
16 by recent research, with a 2023 systematic review and meta-analysis concluding that “compared with  
17 the healthy control group, the ASD group had higher concentrations of Cd, Pb, arsenic, and Hg.  
18 These 4 heavy metals play different roles in the occurrence and progression of ASD.”

19  
20           101.   Repeated associations between early life Toxic Heavy Metal exposure and ASD have  
21 also been observed during the pre-natal timeframe, lending further strength to the findings of post-  
22 natal studies. For example, in a 2021 study by Skogheim and colleagues, the authors prospectively  
23 assessed the relationship between pre-natal metal exposure in various biomarkers and autism risk.  
24 The study concluded that “[r]esults from the present study show several associations between levels  
25 of metals and elements during gestation and ASD and ADHD in children. The most notable ones  
26  
27  
28

1 involved arsenic...mercury...and lead. Our results suggest that even population levels of these  
2 compounds may have negative impacts on neurodevelopment.”

3  
4 102. Similarly, in a study by the research group assessing the New Hampshire Birth  
5 Cohort, the authors evaluated the neurotoxic effects of heavy metals during various stages of  
6 pregnancy and concluded: “Our results support the hypothesis that exposure to...As in mid to late  
7 pregnancy may be neurodevelopmentally harmful.”

8  
9 103. Such results have been replicated in studies throughout the world, including China,  
10 Korea, the U.S., Europe, and Egypt, implicating arsenic, mercury, and lead in pediatric diagnoses of  
11 autism and autistic behaviors, with a 2018 Chinese study concluding: “[t]he results of this study are  
12 consistent with numerous previous studies, supporting an important role for heavy metal exposure,  
13 particularly mercury, in the etiology of ASD.” Indeed, a 2015 Egyptian study noted  
14 “[e]nvironmental exposure to these toxic heavy metals, *at key times in development*, may play a  
15 *casual* role in autism.” (emphasis added).

16  
17 104. Exposure to Toxic Heavy Metals, specifically lead, has also been repeatedly  
18 associated with the development of ADHD in children, as demonstrated by numerous studies.

19  
20 105. No fewer than four large meta-analyses, conducted in four different continents  
21 (North America, America, South America, Europe and Asia), and some employing a cross-sectional  
22 design, have observed a consistent association between various metals and ADHD in children.  
23 Indeed, the authors of the meta-analysis from Spain noted that “the evidence from the studies  
24 allowed us to establish that there is an association between lead and ADHD and that even *low levels*  
25 *of lead raise the risk*.” (emphasis added).

26  
27 106. The findings from the meta-analyses have been replicated in several Chinese studies  
28 from 2006, 2014, and 2018, respectively. Notably, the authors of the 2014 Chinese study observed



1 that “[e]xposure to lead even at low levels correlates with attention-deficit/hyperactivity disorder  
2 (ADHD). However, lead-contaminated environments are often *contaminated with other heavy*  
3 *metals that could exacerbate lead-induced ADHD.*” (emphasis added). This is particularly  
4 relevant—and disturbing—as children who consumed Defendants’ baby foods were repeatedly  
5 exposed to a cocktail of Toxic Heavy Metals that, synergistically, further increased their risk of  
6 developing ADHD.

8 107. Moreover, studies have observed a dose-response relationship between exposure to  
9 Toxic Heavy Metals and ADHD, as demonstrated by the 2016 Spanish study Donzelli, *et al.* Another  
10 2016 cross-sectional study from Spain was conducted on 261 children aged 6-9 to examine the  
11 association between exposure to arsenic and ADHD. After adjusting for potential confounders, the  
12 authors observed a dose-response relationship between urine arsenic levels and inattention and  
13 impulsivity scores, concluding that “[urine arsenic] levels were associated with impaired  
14 attention/cognitive function, *even at levels considered safe.* These results provide additional  
15 evidence that postnatal arsenic exposure impairs neurological function in children.” (emphasis  
16 added.)

19 108. The fact that such results, and many more, have been observed in multiple studies,  
20 conducted by different researchers, at different times, in different parts of the world, in children of  
21 multiple ages, utilizing different study methods (prospective, case-control and cross-sectional  
22 epidemiological analyses) and measuring a variety of end-points (including hair, blood, and urine),  
23 strongly supports a causal relationship between exposure to Toxic Heavy Metals and the  
24 development of ASD and ADHD in children.

26 **B. Defendants’ Baby Foods Contain Toxic Heavy Metals Capable of Interfering with**  
27 **Early Neurodevelopment**  
28

1           109. As illustrated above, Toxic Heavy Metal exposure is capable of inflicting damage to  
2 the developing brain at extremely low doses. And, upon information and belief, Defendants  
3 manufactured and sold baby foods containing Toxic Heavy Metals that can, under certain  
4 circumstances (based upon the genetic susceptibilities, medical history, and other factors of the  
5 exposed child) interfere with a baby's neurodevelopment sufficient to cause conditions such as ASD  
6 and ADHD.

8           110. As an initial matter, the study commissioned by HBBF and discussed above  
9 specifically evaluated the propensity for arsenic exposure through consumption of infant rice cereal  
10 to impact early life neurodevelopment. Following analyses of the levels of arsenic exposure from  
11 consumption of infant rice cereal, the authors concluded "that high consumers of infant rice cereal  
12 (i.e., infants eating three servings per day) eating products currently on the U.S. market would have a  
13 daily arsenic intake of 0.35-0.67  $\mu\text{g/kg bw/day}$ ...per the Tsuji et al. (2015) lower-bound estimate for  
14 an RFD for the neurodevelopmental effects of arsenic (0.4  $\mu\text{g/kg bw/day}$ ), high consumers of infant  
15 rice cereal may also be at risk for this endpoint. Even in average consumers of infant rice cereal  
16 (i.e., one serving per day), our estimates of arsenic intakes (0.15 to 0.29  $\mu\text{g/kg bw/day}$ ) leave little  
17 room for exposures to arsenic from other sources." Thus, consumption of Defendants' baby foods,  
18 including but not limited to infant rice cereal and rice-based snack baby food products manufactured  
19 and sold by Defendants can expose babies to levels of arsenic above that associated with  
20 neurodevelopmental harm in the scientific literature.

22           111. Defendants manufactured and sold baby food products that, with just a couple of  
23 servings, are capable of exposing a baby to lead levels at or above the 2.2  $\mu\text{g/day}$  considered by the  
24 FDA to be associated with neurodevelopmental harm. Each source of lead exposure is cumulative—  
25 making any detectable amount of Toxic Heavy Metal in baby food a contributing factor to potential  
26  
27  
28

1 neurodevelopmental harm.

2        112. Similarly, upon information and belief, Defendant Hain was aware of the neurotoxic  
3 propensities of lead, arsenic, and mercury at low levels, but proceeded to manufacture and sell Baby  
4 Foods containing arsenic and lead levels that, upon information and belief, Hain considered as  
5 capable of inflicting neurodevelopmental harm.  
6

7 **VI. Defendants Knowingly Sold Baby Foods Containing Toxic Heavy Metals and Knew or**  
8 **Should Have Known of the Risks of Such Exposures in Children and Thus Breeched**  
9 **their Duty of Care in Selling Contaminated Baby Foods**

10        113. During the time that Defendants manufactured and sold baby foods in the United  
11 States, the weight of evidence showed that Defendants' baby foods exposed babies and children to  
12 Toxic Heavy Metals. Defendants failed to disclose this risk to consumers through any means.  
13

14        114. As discussed above, both independent testing, the Defendants' internal evaluations of  
15 their baby foods, and the Defendants' representations and disclosures to Congress and the FDA  
16 reveal the presence of Toxic Heavy Metals in Defendants' products. As such, Defendants knew or  
17 should have known that their baby foods contain Toxic Heavy Metals with an attendant risk of  
18 causing neurodevelopmental harm.  
19

20        115. Indeed, independent testing performed in early 2019 demonstrated elevated amounts  
21 of such Toxic Heavy Metals in Baby Food products on the U.S. market, and the HBBF Report  
22 further confirmed such contamination of Defendants' baby foods. And, as the Congressional  
23 investigation found, the Defendants continued to sell their baby foods even after testing of both  
24 ingredients and finished products revealed the presence of Toxic Heavy Metals.  
25

26        116. Moreover, the scientific literature on the dangers of Toxic Heavy Metals—  
27 particularly as it relates to adverse effects on the neurodevelopment of children—have been well  
28 known for decades. Defendants, as manufacturers and sellers of baby foods, are held to the standard

1 of experts and responsible for keeping abreast of the latest scientific developments related are held to  
 2 the dangers of contaminants in their products. Defendants failed to take action to protect vulnerable  
 3 children from exposure to the Toxic Heavy Metals in their foods and, thus, subjected them to the risk  
 4 of brain injury which can manifest as neurodevelopmental disorders such as ASD, ADHD, and  
 5 related *sequalae*.  
 6

7 117. To be clear, the Defendants are able to manufacture baby foods that do not pose such  
 8 a dangerous risk to the health of infants and children by using alternative ingredients, not adding  
 9 certain pre-mix minerals and vitamins high in Toxic Heavy Metals or sampling their ingredients  
 10 from other sources. At the very least, Defendants were under a duty to warn unsuspecting parents of  
 11 the presence of Toxic Heavy Metals in their Baby Foods.  
 12

13 **VII. Defendants' Baby Food Products Were Defective Due to Insufficient Warnings,**  
 14 **Manufacturing Defects, and/or Design Defects to the Extent the Baby Food Products**  
 15 **Contained Detectable Levels of Toxic Heavy Metal**

16 118. All of Defendants' baby food products that contained detectable levels of Toxic  
 17 Heavy Metals (or constituted finished products wherein the ingredients contained detectable levels  
 18 of Toxic Heavy Metals), assuming state of the art analytical testing, were defective as it relates to  
 19 warnings because no Defendant has ever warned about the presence of Toxic Heavy Metals in their  
 20 baby foods. Because discovery is ongoing, a complete list of Defendants' specific baby foods that  
 21 contained detectable levels of Toxic Heavy Metals is not known at this time. Based on publicly  
 22 available testing data, including data reported by HBBF and Congress, the vast majority of  
 23 Defendants' products contain detectable levels of Toxic Heavy Metals in them, rendering them each  
 24 defective as it relates to warnings. Attached as Appendix **A** to this Complaint is a list of the  
 25 Defendants' products now known to be defective. This list, however, is not comprehensive and  
 26 shall be amended as discovery is obtained.  
 27  
 28

1           119. Defendants' baby food products are also defective as manufactured, as they contain  
2 detectable Toxic Heavy Metals which are not supposed to be there, by design. Toxic Heavy Metals  
3 do not provide any nutritional or therapeutic value to infants or fully-grown humans. They are only  
4 poisonous to neurodevelopment. None of these baby food products, by design, should contain Toxic  
5 Heavy Metals in them and, thus, to the extent the products contain detectable levels of Toxic Heavy  
6 Metals in them, those are manufacturing defects. Based on publicly available data, most of  
7 Defendants' baby food products contain some detectable levels of Toxic Heavy Metals in them.  
8 However, as the levels of Defendants' baby food products are not known yet, nor do Plaintiff have a  
9 complete list of Defendants' baby food products or their formulations—information that will be  
10 obtained through discovery—Plaintiff cannot identify each baby food product that contained a  
11 manufacturing defect. However, Appendix A is a running list of baby food products sold by  
12 Defendants.  
13

14           120. If Defendants specifically designed their baby food products to contain Toxic Heavy  
15 Metals, meaning their presence was not the product of a manufacturing defect, then the products  
16 were defective by design. Toxic Heavy Metals should not be present in foods that are being  
17 consumed by infants and products should be designed to not have detectable levels of toxic heavy  
18 metal in them. Such designs are easily accomplished, by only using ingredients that contain non-  
19 detectable levels of Toxic Heavy Metals and by testing finished products, before release, to ensure  
20 they do not contain Toxic Heavy Metals within them. This is possible because there are examples of  
21 Defendants' finished products not containing detectable levels of Toxic Heavy Metals—even if, for  
22 that same products, there are instances where they did. Thus, Defendants were able to design baby  
23 food products to not contain detectable levels of toxic heavy metals, and to the extent that each  
24 Defendants' design contemplated there being detectable levels of Toxic Heavy Metals in baby food,  
25  
26  
27  
28

1 the design, itself, was defective. Because Plaintiff does not know the Defendants' intended design  
2 for their baby food products—as there has been no discovery obtained to date concerning product  
3 formulation, product/ingredient specifications, and testing methodologies/capabilities—Plaintiff  
4 cannot specify which baby food products were defectively designed versus which ones were not.  
5 That said, Appendix A, a running list of the Defendants' baby food products that, with further  
6 discovery, may yield information that will allow Plaintiff to identify whether the product was  
7 defectively designed.  
8

9           121. Whether the Defendants' products were defective due to inadequate warnings,  
10 manufacturing errors, or by design, the existing publicly available evidence indicates that  
11 consumption of Defendants' baby food products can expose infants to Toxic Heavy Metals, and that  
12 depending on specific milieu of products consumed by each Plaintiff and each Plaintiff's specific  
13 susceptibility and circumstances, Defendants' baby food products contributed to each Plaintiff's  
14 Toxic Heavy Metal burden during critical period of infant neurodevelopment. Plaintiff, thus, alleges  
15 that this cumulative exposure from Defendants' products to Toxic Heavy Metals, substantially  
16 contributed to causing neurodevelopmental harm that manifested as ASD and/or ADHD. Moreover,  
17 each Plaintiff alleges that had these baby food products not been defective—by having sufficient  
18 warnings, being correctly manufactured, and/or designed properly—each Plaintiff would not have  
19 been exposed to levels of Toxic Heavy Metals in Defendants' baby food products that would have  
20 contributed to the neurodevelopmental harm that manifested as ASD and/or ADHD.  
21  
22

#### 23 **VIII. Exemplary/Punitive Damages Allegations**

24           122. Defendants' conduct as alleged herein was done with reckless disregard for human  
25 life, oppression, and malice. Defendants' conduct is particularly reprehensible given that their toxic  
26 foods were directed at vulnerable babies—a population group far more susceptible than adults to the  
27  
28

1 neurotoxic dangers of heavy metals.

2       123. Defendants were fully aware of the safety risks of Contaminated Baby Foods,  
3 particularly the dangerous potential of Toxic Heavy Metals on neurodevelopment in infants and  
4 children. Nonetheless, Defendants deliberately crafted their label, marketing, and promotion to  
5 mislead consumers. Indeed, Defendants repeatedly market their baby foods as safe for consumption  
6 and go so far as claiming that they adhere to “the strictest standards in the world;” and provide  
7 “baby’s food full of nutrition while meeting standards strict enough for tiny tummies,” as well as  
8 other statements and representations that hold out their baby foods as safe for consumption by  
9 infants. Indeed, each Defendant falsely reassured parents/guardians/caregivers that their baby foods  
10 would foster healthy neurodevelopment when consumed even though they knew their baby foods  
11 exposed infants’ developing brains to potent neurotoxic heavy metals. In actual fact, as discussed  
12 above, Defendants routinely sold Contaminated Baby Foods, regularly flouted their own internal  
13 limits of Toxic Heavy Metals and failed to disclose to consumers that their products contained such  
14 dangerous contaminants.  
15

16       124. This was not done by accident or through some justifiable negligence. Rather,  
17 Defendants knew they could profit by convincing consumers that their baby foods were healthy and  
18 safe for infants, and that full disclosure of presence and/or risks of the Toxic Heavy Metals present  
19 in the baby foods would limit the amount of money Defendants would make selling the products.  
20 Defendants’ object was accomplished not only through a misleading label, but through a  
21 comprehensive scheme of selective misleading research and testing, failure to test, false advertising,  
22 and deceptive omissions as more fully alleged throughout this Complaint.  
23 Parents/guardians/caregivers were denied the right to make an informed decision about whether to  
24 purchase Defendants’ baby food for their babies without knowing the full risks attendant to that use.  
25  
26  
27  
28

1 Such conduct was done with conscious disregard of Plaintiff's welfare and rights.

2 **CAUSE OF ACTION**

3 **I. COUNT I: STRICT PRODUCTS LIABILITY – FAILURE TO WARN**

4 125. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as  
5 if fully stated herein.

6  
7 126. At all relevant times, Defendants engaged in the business of researching, testing,  
8 developing, designing, manufacturing, labeling, marketing, selling, inspecting, distributing, and  
9 promoting baby foods, which are defective and unreasonably dangerous to consumers, including  
10 Plaintiff, because they do not contain adequate warnings or instructions concerning the dangerous  
11 characteristics of baby foods in the form of the presence of Toxic Heavy Metals. These actions were  
12 under the ultimate control and supervision of Defendants. At all relevant times, Defendants  
13 registered, researched, manufactured, distributed, marketed, and sold baby foods and aimed at a  
14 consumer market.

15  
16 127. Defendants researched, tested, developed, designed, manufactured, labeled, marketed,  
17 sold, inspected, distributed, and promoted, and otherwise released into the stream of commerce their  
18 Contaminated Baby Foods, and in the course of same, directly advertised or marketed the products  
19 to consumers and end users, including Plaintiff, and therefore had a duty to warn about the presence  
20 of and risks associated with exposure to Toxic Heavy Metals from the consumption of Contaminated  
21 Baby Foods.

22  
23 128. At all relevant times, Defendants had a duty to properly test, develop, design,  
24 manufacture, inspect, package, label, market, promote, sell, and distribute, maintain, supply, provide  
25 proper warnings, and take such steps as necessary to ensure their Contaminated Baby Foods did not  
26 cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a  
27 continuing duty to warn Plaintiff of dangers associated with exposure to Toxic Heavy Metals from  
28



1 consumption of the Contaminated Baby Foods. Defendants, as a manufacturer, seller, or distributor  
2 of food, are held to the knowledge of an expert in the field.

3       129. At the time of manufacture, Defendants could have provided the warnings or  
4 instructions regarding the full and complete risks of exposure to Toxic Heavy Metals in the  
5 Contaminated Baby Foods because they knew or should have known of the unreasonable risks of  
6 harm associated with the use of and/or exposure to such toxins.

7  
8       130. At all relevant times, Defendants failed and deliberately refused to investigate, study,  
9 test, or promote the safety or to minimize the dangers to users and consumers of their product and to  
10 those who would foreseeably use or be harmed by exposure to the Toxic Heavy Metals in  
11 Defendants' Baby Foods.

12  
13       131. Even though Defendants knew or should have known that the presence of Toxic  
14 Heavy Metals in Contaminated Baby Foods posed a risk of harm, they failed to exercise reasonable  
15 care to warn of the dangerous risks associated with use and exposure to the toxins in the products.  
16 The neurotoxic characteristic of Toxic Heavy Metals contained in Defendants' Contaminated Baby  
17 Foods, as described above, were known to Defendants, or scientifically knowable to Defendants  
18 through appropriate research and testing by known methods, at the time they distributed, supplied, or  
19 sold the products, and were not known to end users and consumers, such as Plaintiff. The product  
20 warnings for Contaminated Baby Foods in effect during the time period Plaintiff consumed those  
21 foods were inadequate, both substantively and graphically, to alert consumers to the presence of and  
22 health risks associated with exposure to the Toxic Heavy Metals from Contaminated Baby Food  
23 consumption.

24  
25  
26       132. At all relevant times, Defendants' Contaminated Baby Foods reached the intended  
27 consumers, handlers, and users or other persons coming into contact with these products, including  
28

1 Plaintiff, without substantial change in their condition as manufactured, sold, distributed, labeled,  
2 and marketed by Defendants.

3       133. Plaintiff was exposed to the Toxic Heavy Metals in Defendants' Contaminated Baby  
4 Foods without knowledge of the potential for such exposure to Toxic Heavy Metals from  
5 consumption of the products and the dangerous characteristics of the toxins.  
6

7       134. At all relevant times, Plaintiff was exposed to the Toxic Heavy Metals in the  
8 Defendants' Contaminated Baby Foods while consuming the foods for their intended or reasonably  
9 foreseeable purposes, without knowledge of their dangerous characteristics.  
10

11       135. Plaintiff could not have reasonably discovered the defects and risks associated with  
12 exposure to the Toxic Heavy Metals in the Contaminated Baby Foods prior to or at the time of  
13 Plaintiff consuming those foods. Plaintiff relied upon the skill, superior knowledge, and judgment of  
14 Defendants to know about and disclose serious health risks associated with exposure to the toxins in  
15 Defendants' products.  
16

17       136. The information that Defendants did provide or communicate failed to contain  
18 relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff to  
19 avoid consuming the products and, in turn, exposure to the Toxic Heavy Metals. Instead,  
20 Defendants disseminated information that was inaccurate, false, and misleading, and which failed to  
21 communicate accurately or adequately the comparative severity, duration, and extent of the risk of  
22 injuries with use of and/or exposure to the Toxic Heavy Metals in the Contaminated Baby Foods;  
23 continued to aggressively promote the safety of their products, even after they knew or should have  
24 known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise  
25 suppressed, through aggressive marketing and promotion, any information or research about the  
26 risks and dangers of exposure to Toxic Heavy Metals from consumption of Contaminated Baby  
27  
28

1 Foods.

2       137. This alleged failure to warn is not limited to the information contained on  
3 Contaminated Baby Foods labeling. The Defendants were able, in accordance with federal law, to  
4 comply with relevant Florida state law, including §768.81 Fla. Stat. (2024), disclosing the known  
5 risks associated with exposure to Heavy Metals in Contaminated Baby Foods through other non-  
6 labeling mediums, i.e., promotion, advertisements, public service announcements, and/or public  
7 information sources. But the Defendants did not disclose these known risks through any medium.  
8 The ability to provide such warnings is not prohibited by any federal law.  
9

10  
11       138. Furthermore, Defendants possess a First Amendment Right to make truthful  
12 statements about the products they sell, and no law could lawfully restrict that constitutional right.  
13 This included making statements about the presence of and risks associated with Toxic Heavy  
14 Metals in Contaminated Baby Foods.  
15

16       139. Had Defendants provided adequate warnings and instructions and properly disclosed  
17 and disseminated the risks associated with exposure to the toxins in their Contaminated Baby Foods,  
18 Plaintiff could have avoided the risk of developing injuries and could have obtained or used  
19 alternative products. However, as a result of Defendants' concealment of the dangers posed by the  
20 Toxic Heavy Metals in their Contaminated Baby Foods, Plaintiff could not have averted their  
21 exposures.  
22

23       140. Defendants' conduct, as described above, was reckless. Defendants risked the lives  
24 of babies and children, including Plaintiff, with knowledge of the safety problems associated with  
25 Contaminated Baby Foods, and suppressed this knowledge from the general public. Defendants  
26 made conscious decisions not to warn or inform the unsuspecting public.  
27

28       141. The Defendants' lack of adequate warnings and instructions accompanying their

1 Contaminated Baby Foods caused Plaintiff's injuries.

2 142. As a direct and proximate result of the Defendants' failure to provide an adequate  
3 warning of the risks of exposure to the Toxic Heavy Metals in their Contaminated Baby Foods,  
4 Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment,  
5 loss of enjoyment of life, economic loss and damages including, but not limited to past and future  
6 medical expenses, lost income, and other damages.

7  
8 143. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in  
9 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all  
10 such other and further relief as this Court deems just and proper.

11  
12 **II. COUNT II: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT**

13 144. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as  
14 if fully stated herein.

15 145. At all times herein mentioned, Defendants designed, manufactured, tested, marketed,  
16 sold, handled, and distributed the Contaminated Baby Foods consumed by Plaintiff.

17 146. At all relevant times, the Contaminated Baby Foods consumed by Plaintiff were  
18 expected to and did reach Plaintiff without a substantial change in their condition as manufactured,  
19 handled, distributed, and sold by Defendants.

20 147. At all relevant times, the Contaminated Baby Foods consumed by Plaintiff were used  
21 in a manner that was foreseeable and intended by Defendants.

22 148. The Contaminated Baby Foods consumed by Plaintiff were not reasonably safe for  
23 their intended use and were defective with respect to their manufacture, as described herein, in that  
24 Defendants deviated materially from their design and manufacturing specifications and/or such  
25  
26  
27  
28

1 design and manufacture posed an unreasonable risk of harm to Plaintiff. <sup>1</sup>Baby food should not, by  
2 design, contain any detectable levels of Toxic Heavy Metals in them. Thus, Defendants'  
3 Contaminated Baby Foods contain manufacturing defects.

4  
5 149. The Defendants' Contaminated Baby Foods contained Toxic Heavy Metals because,  
6 while in the control and possession of Defendants, they manufactured ingredients and used  
7 manufacturing processes that result in the finished product being contaminated with Toxic Heavy  
8 Metals. Had Defendants properly manufactured (directly or through co-manufacturers) the baby  
9 foods, they would not have contained detectable levels of Toxic Heavy Metals in them and, thus,  
10 would not have contained a manufacturing defect.

11  
12 150. Nothing under federal law limited or restricted Defendants from taking action to  
13 reduce or eliminate the Toxic Heavy Metals from being present in their baby foods.

14 151. This manufacturing defect caused Plaintiff to be exposed to Toxic Heavy Metals  
15 through ingestion of the Contaminated Baby Foods which, in turn, caused neurodevelopmental harm  
16 that manifested as ASD.

17  
18 152. The exposure to the Toxic Heavy Metals in the Contaminated Baby Foods creates  
19 risks to the health and safety of babies that are far more significant than the risks posed by non-  
20 Contaminated Baby Food products, and which far outweigh the utility of the Contaminated Baby  
21 Foods products because of Defendants' manufacturing defects.

22  
23 153. Defendants have intentionally and recklessly manufactured the Contaminated Baby  
24 Foods with wanton and willful disregard for the rights and health of Plaintiff, and with malice,  
25 placing their economic interests above the health and safety of Plaintiff.

---

26  
27  
28 <sup>1</sup> If, through discovery and further litigation, it is discovered that Defendants' baby food products  
contained detectable levels of Toxic Heavy Metals by design, then Plaintiff will pursue a design  
defect claim (Count III) in the alternative.

1           154. As a direct and proximate result of the Defendants' defective manufacture of the  
 2 Contaminated Baby Foods, Plaintiff has been injured, sustained severe and permanent pain,  
 3 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including,  
 4 but not limited to medical expenses, lost income, and other damages.

6           155. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in  
 7 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all  
 8 such other and further relief as this Court deems just and proper.

9 **III. COUNT III: STRICT PRODUCTS LIABILITY – DESIGN DEFECT**

10           156. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as  
 11 if fully stated herein.

13           157. At all times herein mentioned, Defendants designed, manufactured, tested, marketed,  
 14 sold, handled, and distributed the Contaminated Baby Foods consumed by Plaintiff. These actions  
 15 were under the ultimate control and supervision of Defendants.

17           158. At all relevant times, Defendants' Baby Food products were designed and labeled in  
 18 an unsafe, defective, and inherently dangerous manner that was dangerous for use or consumption by  
 19 infants and babies, including Plaintiff.

20           159. Defendants' Contaminated Baby Food products as researched, tested, developed,  
 21 designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants  
 22 were defective in design and formulation in that, when they were placed into the stream of  
 23 commerce, they were unreasonably dangerous and dangerous to an extent beyond that which an  
 24 ordinary consumer would contemplate.

26           160. Defendants' Contaminated Baby Food products, as researched, tested, developed,  
 27 designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants  
 28

1 were defective in design and formulation in that, when they left the hands of Defendants, the  
2 foreseeable risks exceeded the alleged benefits associated with their design and formulation.

3  
4 161. At all relevant times, the Contaminated Baby Food products consumed by Plaintiff  
5 were expected to and did reach Plaintiff without a substantial change in its condition as designed,  
6 manufactured, handled, distributed, and sold by Defendants.

7  
8 162. At all relevant times, Defendants knew or had reason to know that their Contaminated  
9 Baby Food products were defective and were inherently dangerous and unsafe when used in the  
10 manner instructed and provided by Defendants.

11  
12 163. Therefore, at all relevant times, Defendants' Baby Food products, as researched,  
13 tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold  
14 and marketed by Defendants were defective in design and formulation, in one or more of the  
15 following ways:

- 16 A. When placed in the stream of commerce, Defendants' Contaminated Baby Food products  
17 were unreasonably dangerous in that they contained Toxic Heavy Metals that posed a risk  
18 of causing interference with neurodevelopment in babies that manifests as the  
19 neurodevelopmental disorders ASD, ADHD and related sequelae when used in a  
20 reasonably anticipated manner;  
21  
22 B. When placed in the stream of commerce, Defendants' designed Contaminated Baby Food  
23 products to contain unreasonably dangerous design defects and were not reasonably safe  
24 when used in a reasonably anticipated or intended manner;  
25  
26 C. Defendants, by design, did not sufficiently test, investigate, or study their Contaminated  
27 Baby Food products;  
28

1 D. Exposure to the Toxic Heavy Metals in Defendants' Contaminated Baby Food products  
2 present a risk of harmful effects that outweigh any potential utility stemming from their  
3 use;

4 E. Defendants, by design, did not conduct adequate post-marketing surveillance of their  
5 Contaminated Baby Food products which would have alerted the public to risks; and

6 F. Defendants could have employed safer alternative designs and formulations for  
7 Contaminated Baby Foods, such as ensuring the baby food did not have any detectable  
8 level of Toxic Heavy Metals.  
9

10 164. Plaintiff consumed Defendants' Contaminated Baby Food products in an intended or  
11 reasonably foreseeable manner without knowledge of their dangerous characteristics.  
12

13 165. Defendants' Contaminated Baby Food products were and are more dangerous than  
14 alternative products, and Defendants could have designed their Contaminated Baby Food products to  
15 avoid harm to children. Indeed, at the time Defendants designed the Contaminated Baby Food  
16 products, the state of the industry's scientific knowledge was such that a less risky design or  
17 formulation was attainable.  
18

19 166. At the time the Contaminated Baby Food products left Defendants' control, there was  
20 a practical, technically feasible, and safer alternative design that would have prevented the harm  
21 without substantially impairing the reasonably anticipated or intended function of Defendants'  
22 Contaminated Baby Foods.  
23

24 167. Defendants intentionally and recklessly defectively designed the Contaminated Baby  
25 Foods with wanton and willful disregard for the rights and health of Plaintiff, and with malice,  
26 placing their economic interests above the health and safety of Plaintiff.  
27

28 168. The design defects in Defendants' Contaminated Baby Foods were substantial factors



1 in causing Plaintiff injuries.

2       169. As a direct and proximate result of the Defendants' defective design of the  
3 Contaminated Baby Foods, Plaintiff has been injured, sustained severe and permanent pain,  
4 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including,  
5 but not limited to medical expenses, lost income, and other damages.  
6

7       170. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in  
8 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all  
9 such other and further relief as this Court deems just and proper.  
10

11 **IV. COUNT IV: NEGLIGENCE – FAILURE TO WARN**

12       171. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as  
13 if fully stated herein.

14       172. At all relevant times, Defendants engaged in the business of testing, developing,  
15 designing, manufacturing, marketing, selling, distributing, and promoting baby foods. Defendants  
16 knew, or, by the exercise of reasonable care, should have known that their Contaminated Baby  
17 Foods are not accompanied with adequate warnings concerning the dangerous characteristics of  
18 exposure to Toxic Heavy Metals from consumption. These actions were under the ultimate control  
19 and supervision of Defendants.  
20

21       173. Defendants researched, developed, designed, tested, manufactured, inspected, labeled,  
22 distributed, marketed, promoted, sold, and otherwise released into the stream of commerce their  
23 Contaminated Baby Foods, and in the course of same, directly advertised or marketed the products  
24 to consumers and end users, including Plaintiff, and therefore had a duty to warn of the risks  
25 associated with the presence of and exposure to Toxic Heavy Metals from consumption of  
26 Contaminated Baby Foods.  
27  
28

1           174. At all relevant times, Defendants had a duty to properly test, develop, design,  
2 manufacture, inspect, package, label, market, promote, sell, distribute, maintain, supply, provide  
3 proper warnings, and take such steps as necessary to ensure their Contaminated Baby Foods did not  
4 cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a  
5 continuing duty to warn Plaintiff of dangers associated with the presence of and exposure to Toxic  
6 Heavy Metals from consumption of Contaminated Baby Foods. Defendants, as a manufacturer,  
7 seller, or distributor of food products, are held to the knowledge of an expert in the field.  
8

9           175. At the time of manufacture, Defendants could have provided warnings regarding the  
10 presence of and risks of exposure to Toxic Heavy Metals from consumption of Contaminated Baby  
11 Foods because they knew or should have known exposure to Toxic Heavy Metals from consumption  
12 of Contaminated Baby Foods was dangerous, harmful and injurious when the Contaminated Baby  
13 Foods were consumed by Plaintiff in a reasonably foreseeable manner.  
14

15           176. At all relevant times, Defendants failed and deliberately refused to investigate, study,  
16 test, or promote the safety or to minimize the dangers to users and consumers of their products and  
17 to those who would foreseeably use or be harmed by Defendants' Contaminated Baby Foods.  
18

19           177. Defendants knew or should have known that exposure to Toxic Heavy Metals from  
20 consumption of Contaminated Baby Foods posed a risk of harm, but failed to exercise reasonable  
21 care to warn of the dangerous risks associated with use and exposure to the toxins in the products.  
22 The dangerous propensities of exposure to Toxic Heavy Metals from consumption of the  
23 Contaminated Baby Foods, as described above, were known to Defendants, or scientifically  
24 knowable to Defendants through appropriate research and testing by known methods, at the time  
25 they distributed, supplied, or sold the products, and were not known to end users and consumers,  
26 such as the Plaintiff.  
27  
28

1           178. At all relevant times, Plaintiff was exposed to Toxic Heavy Metals through  
2 consumption of the Contaminated Baby Foods while using the products for their intended or  
3 reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

4  
5           179. Defendants knew or should have known that the non-extant warnings disseminated  
6 with their Contaminated Baby Foods were inadequate, failed to communicate adequate information  
7 on the presence of and dangers of exposure to toxins contained therein, and failed to communicate  
8 warnings and instructions that were appropriate and adequate to render the products safe for their  
9 ordinary, intended and reasonably foreseeable uses.

10  
11           180. The information that Defendants did provide or communicate failed to contain  
12 relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff to  
13 avoid using the product and, in turn, prevented exposure to the Toxic Heavy Metals contained  
14 therein. Instead, Defendants disseminated information that was inaccurate, false, and misleading,  
15 and which failed to communicate accurately or adequately the comparative severity, duration, and  
16 extent of the risk of injuries with use of and/or exposure to the Toxic Heavy Metals in the  
17 Contaminated Baby Foods; continued to aggressively promote the efficacy of their products, even  
18 after they knew or should have known of the unreasonable risks from use or exposure to the toxins  
19 contained therein; and concealed, downplayed, or otherwise suppressed, through aggressive  
20 marketing and promotion, any information or research about the risks and dangers of exposure to  
21 Toxic Heavy Metals from consumption of the Contaminated Baby Foods.

22  
23  
24           181. A reasonable company under the same or similar circumstance would have warned  
25 and instructed of the dangers of exposure to Toxic Heavy Metals from consumption of Contaminated  
26 Baby Foods.

27  
28           182. This alleged failure to warn is not limited to the information contained on the labeling

1 of Defendants' Contaminated Baby Foods. Defendants were able, in accord with federal law, to  
2 comply with relevant state law by disclosing the known risks associated with exposure to Toxic  
3 Heavy Metals from consumption of Contaminated Baby Foods through other non-labeling mediums,  
4 i.e., promotion, advertisements, public service announcements, and/or public information sources.  
5 But the Defendants did not disclose these known risks through any medium.  
6

7 183. Furthermore, Defendants possess a First Amendment Right to make truthful  
8 statements about the products they sell, and no law could lawfully restrict that constitutional right.  
9

10 184. Had Defendants provided adequate warnings and instructions and properly disclosed  
11 and disseminated the risks associated with the presence of and exposure to Toxic Heavy Metals in  
12 the Contaminated Baby Foods, Plaintiff could have avoided the risk of developing injuries and could  
13 have obtained or used alternative products. However, as a result of Defendants' concealment of the  
14 dangers posed by their Contaminated Baby Foods, Plaintiff could not have averted their injuries.  
15

16 185. Defendants' conduct, as described above, was reckless. Defendants risked the lives of  
17 consumers and users of their products, including Plaintiff, with knowledge of the safety problems  
18 associated with Contaminated Baby Foods, and suppressed this knowledge from the general public.  
19 Defendants made conscious decisions not to warn or inform the unsuspecting public.  
20

21 186. The Defendants' lack of adequate warnings and instructions accompanying their  
22 Contaminated Baby Foods were a substantial factor in causing Plaintiff's injuries.  
23

24 187. As a direct and proximate result of the Defendants' failure to provide an adequate  
25 warning of the risks of exposure to Toxic Heavy Metals from consumption of Contaminated Baby  
26 Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability,  
27 impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past  
28 and future medical expenses, lost income, and other damages.

1           188.   **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in  
2 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all  
3 such other and further relief as this Court deems just and proper.

4  
5   **V.     COUNT V: NEGLIGENCE - MANUFACTURING**

6           189.   Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as  
7 if fully stated herein.

8           190.   At all relevant times, the Defendants manufactured, tested, marketed, sold, and  
9 distributed the Contaminated Baby Foods that Plaintiff consumed.

10           191.   The Defendants had a duty to exercise reasonable care, in the manufacturing, testing,  
11 marketing, sale, and distribution of baby foods.

12           192.   The Defendants knew or, by the exercise of reasonable care, should have known, that  
13 exposure to Toxic Heavy Metals from consumption of Contaminated Baby Foods rendered the foods  
14 carelessly manufactured, dangerous, harmful and injurious when used by Plaintiff in a reasonably  
15 foreseeable manner.

16           193.   The Defendants knew or, by the exercise of reasonable care, should have known,  
17 ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of  
18 exposure to Toxic Heavy Metals from consumption of Contaminated Baby Foods.

19           194.   Without limitation, examples of the manner in which Defendants breached their duty  
20 to exercise reasonable care in manufacturing Contaminated Baby Foods, included:

- 21           A. Failure to adequately inspect/test the Contaminated Baby Foods, and their ingredients,  
22           during and after the manufacturing process;  
23           B. Failure to implement procedures that would reduce or eliminate Toxic Heavy Metals in  
24           baby foods;  
25  
26  
27  
28

1 C. Failure to investigate suppliers and ingredient sources to reduce and eliminate the risk of  
2 ingredients containing Toxic Heavy Metals; and

3 D. Failure to avoid using ingredients free from, or which contain far less, Toxic Heavy  
4 Metals to manufacture baby food.  
5

6 195. A reasonable manufacturer under the same or similar circumstances would have  
7 implemented appropriate manufacturing procedures to better ensure the quality and safety of their  
8 product.

9 196. Plaintiff was harmed directly and proximately by the Defendants' failure to use  
10 reasonable care in the manufacture of their Contaminated Baby Foods. Such harm includes  
11 exposure to Toxic Heavy Metals, which can cause or contribute to interference with early  
12 neurodevelopment which manifests as ASD, ADHD, and related *sequelae*.  
13

14 197. Defendants' improper manufacturing of Baby Foods was willful, wanton, malicious,  
15 and conducted with reckless disregard for the health and safety of users of the Contaminated Baby  
16 Foods, including Plaintiff.  
17

18 198. The defects in Defendants' Contaminated Baby Foods were substantial factors in  
19 causing Plaintiff's injuries.

20 199. As a direct and proximate result of the Defendants' improper manufacturing of  
21 Contaminated Baby Foods, Plaintiff has been injured, sustained severe and permanent pain,  
22 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including,  
23 but not limited to past and future medical expenses, lost income, and other damages.  
24

25 200. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in  
26 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all  
27 such other and further relief as this Court deems just and proper.  
28

1 **VI. COUNT VI: NEGLIGENCE – PRODUCT DESIGN**

2 201. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as  
3 if fully stated herein.

4 202. Defendants knew or, by the exercise of reasonable care, should have known, ordinary  
5 consumers such as Plaintiff would not have realized the potential risks and dangers of Contaminated  
6 Baby Foods.

7 203. The Defendants owed a duty to all reasonably foreseeable users to design a safe  
8 product.

9 204. The Defendants breached their duty by failing to use reasonable care in the design of  
10 Contaminated Baby Foods because the products exposed babies to Toxic Heavy Metals.

11 205. The Defendants breached their duty by failing to use reasonable care in the design of  
12 Contaminated Baby Foods by negligently designing the foods with ingredients and/or components  
13 contaminated with Toxic Heavy Metals.

14 206. The Defendants breached their duty by failing to use reasonable care in the design of  
15 Contaminated Baby Foods by negligently designing and formulation, in one or more of the  
16 following ways:

17 A. When placed in the stream of commerce, Defendants' Contaminated Baby Foods were  
18 defective in design and formulation, and, consequently, dangerous to an extent beyond  
19 that which an ordinary consumer would contemplate;

20 B. When placed in the stream of commerce, Defendants' Contaminated Baby Foods were  
21 unreasonably dangerous in that they were hazardous and posed a risk of  
22 neurodevelopmental disorders and other serious illnesses when used in a reasonably  
23 anticipated manner;

1 C. When placed in the stream of commerce, Defendants' Contaminated Baby Foods  
2 contained unreasonably dangerous design defects and were not reasonably safe when  
3 used in a reasonably anticipated or intended manner;

4 D. Defendants did not sufficiently test, investigate, or study their Contaminated Baby Foods  
5 and, specifically, the content of Toxic Heavy Metals in the ingredients used to  
6 manufacture the foods and/or the finished products;

7 E. Defendants did not sufficiently test, investigate, or study their Contaminated Baby Foods  
8 and, specifically, the ability for those foods to expose babies to Toxic Heavy Metals; and  
9

10 F. Exposure to the Toxic Heavy Metals in Contaminated Baby Foods presents a risk of  
11 harmful effects that outweigh any potential utility stemming from the use of the products;  
12

13 207. Defendants knew or should have known at the time of marketing Contaminated Baby  
14 Foods that exposure to Toxic Heavy Metals contained in the Baby Foods could result in interference  
15 with early neurodevelopment that that manifests as ASD, ADHD and other severe illnesses and  
16 injuries.  
17

18 208. Defendants, by design, did not conduct adequate post-marketing surveillance of their  
19 Contaminated Baby Foods.

20 209. Defendants could have employed safer alternative designs and formulations. For  
21 example, the Defendants could have avoided use of certain ingredients contaminated with Toxic  
22 Heavy Metals, avoided using pre-mix vitamins contaminated with Toxic Heavy Metals, and/or  
23 sampled their ingredients from other sources.  
24

25 210. The Defendants breached their duty by failing to use reasonable care by failing to use  
26 cost effective, reasonably feasible alternative designs. There was a practical, technically feasible,  
27 and safer alternative design that would have prevented the harm without substantially impairing the  
28



1 reasonably anticipated or intended function of Defendants' Contaminated Baby Foods.

2       211. A reasonable company under the same or similar circumstances would have designed  
3 a safer product.

4       212. Plaintiff was harmed directly and proximately by the Defendants' failure to use  
5 reasonable care in the design of their Contaminated Baby Foods. Such harm includes exposure to  
6 Toxic Heavy Metals, which can cause or contribute to interference with neurodevelopment that  
7 manifests as ASD, ADHD, and related *sequalae*.

8       213. Defendants' defective design of Contaminated Baby Foods was willful, wanton,  
9 malicious, and conducted with reckless disregard for the health and safety of consumers of the Baby  
10 Foods, including Plaintiff.

11       214. The defects in Defendants' Contaminated Baby Foods were substantial factors in  
12 causing Plaintiff's injuries.

13       215. As a direct and proximate result of the Defendants' negligent design of the  
14 Contaminated Baby Foods, Plaintiff have been injured, sustained severe and permanent pain,  
15 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including,  
16 but not limited to past and future medical expenses, lost income, and other damages.

17       216. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in  
18 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all  
19 such other and further relief as this Court deems just and proper.

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24 **VII. COUNT VII: GENERAL NEGLIGENCE**

25       217. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as  
26 if fully stated herein.

27       218. Plaintiff pleads claims for negligence under all theories that may be actionable under  
28

1 §768.81 Fla. State. (2024).

2 219. Defendants owed Plaintiff a duty to act with reasonable care.

- 3 A. Defendants owed a duty because they distributed and promoted their products as safe for  
4 children to consume.
- 5 B. Defendants owed a duty because their conduct created a risk of harm to Plaintiff and caused  
6 Plaintiff actual harm.
- 7 C. Defendants owed a duty because the risk of harm to Plaintiff was embedded in, and an  
8 inherent component of, their negligent business practices.
- 9 D. Defendants owed a duty because they designed, manufactured, controlled, distributed, and  
10 sold their products to Plaintiff.
- 11
- 12

13 220. Defendants breached their duty to Plaintiff.

14 221. Defendants' negligence includes, but is not limited to, their marketing, designing  
15 manufacturing, producing, supplying, inspecting, testing, selling and/or distributing Contaminated  
16 Baby Foods in one or more of the following respects:

- 17
- 18 A. Failure to implement procedures that would reduce or eliminate Toxic Heavy Metals in baby  
19 foods;
- 20 B. Failure to investigate suppliers and ingredient sources to reduce and eliminate the risk of  
21 ingredients containing Toxic Heavy Metals; and
- 22 C. Failure to avoid using ingredients free from, or which contain far less, Toxic Heavy Metals to  
23 manufacture baby food.
- 24 D. When placed in the stream of commerce, Defendants' Contaminated Baby Foods were  
25 defective in design and formulation, and, consequently, dangerous to an extent beyond that  
26 which an ordinary consumer would contemplate;
- 27
- 28

1 E. When placed in the stream of commerce, Defendants' Contaminated Baby Foods were  
2 unreasonably dangerous in that they were hazardous and posed a risk of neurodevelopmental  
3 disorders and other serious illnesses when used in a reasonably anticipated manner;

4 F. When placed in the stream of commerce, Defendants' Contaminated Baby Foods contained  
5 unreasonably dangerous design defects and were not reasonably safe when used in a  
6 reasonably anticipated or intended manner;

7 G. Defendants, by design, did not conduct adequate post-marketing surveillance of their  
8 Contaminated Baby Food products which would have alerted the public to risks; and

9 H. Defendants did not sufficiently test, investigate, or study their Contaminated Baby Foods  
10 and, specifically, the ability for those foods to expose babies to Toxic Heavy Metals;

11 I. Defendants could have employed safer alternative designs and formulations for  
12 Contaminated Baby Foods, such as ensuring the baby food did not have any detectable level  
13 of Toxic Heavy Metal.

14 J. Defendants did not sufficiently test, investigate, or study their Contaminated Baby Foods  
15 and, specifically, the content of Toxic Heavy Metals in the ingredients used to manufacture  
16 the foods and/or the finished products; and

17 K. Exposure to the Toxic Heavy Metals in Contaminated Baby Foods presents a risk of harmful  
18 effects that outweigh any potential utility stemming from the use of the products;

19 222. Defendants knew or should have known that their products contained detectable  
20 levels of heavy metals that created an unreasonable risk of harm to children who consumed their  
21 products.

22 223. At all relevant times, the Defendants knew or should have known that the Products  
23 were unreasonably dangerous and defective when put to their reasonably anticipated use.  
24  
25  
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1           224. As a proximate result of Defendants' negligence, Plaintiff has been injured, sustained  
2 severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic  
3 loss, and damages including, but not limited to past and future medical expenses, lost income, and  
4 other damages.  
5

6           225. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in  
7 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all  
8 such other and further relief as this Court deems just and proper.  
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**JURY TRIAL DEMAND**

226. Plaintiff demands a trial by jury on all the triable issues within this pleading.

**PRAYER FOR RELIEF**

227. **WHEREFORE**, Plaintiff requests that the Court enter judgment in Plaintiff's favor and against the Defendants for:

- a. actual or compensatory damages in such amount to be determined at trial and as provided by applicable law;
- b. exemplary and punitive damages sufficient to punish and deter the Defendants and others from future wrongful practices;
- c. pre-judgment and post-judgment interest;
- d. costs including reasonable attorneys' fees, court costs, and other litigation expenses; and
- e. any other relief the Court may deem just and proper.

DATED this 2<sup>nd</sup> Day of August, 2024.

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